



The Finnish spine register (FinSpine): development, design, validation and utility

Johan Marjamaa¹ · Jukka Huttunen² · Jyrki Kankare³ · Antti Malmivaara⁴ · Katri Perna⁵ · Jyrki Salmenkivi³ · Liisa Pekkanen⁶

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Abstract

Purpose Our aim was to develop a nationwide, computer-based, Spine Register (FinSpine) for monitoring surgical activity, quality of surgery, long-term outcomes, and effectiveness of treatment. In this paper, we describe our experiences in the development and implementation of the register.

Methods The register was developed by a steering group, consisting of orthopedic surgeons and neurosurgeons from the whole country. We strived to develop a register which would be in active use by spine surgeons and enable collection of Patient Reported Outcome and Experience Measures (PROMs and PREMs) automatically and prospectively. We are actively promoting the use of the register in order to gain a nationwide coverage and achieve high response-rates from both surgeons and patients.

Results The use of FinSpine started in 2016 and it has been granted continuous funding from the Finnish Institute for Health and Welfare from the 1st of January 2023 onwards. Currently the register is used by 19/23 (83%) public hospitals and the use is expanding to private hospitals as well. The response-rate of surgeons is currently 80%. The response-rate of patients is on average 56% but reaches up to 90% in hospitals using register-coordinators.

Conclusion The use of FinSpine is increasing. By gaining a larger coverage and completeness, the data can be used for research purposes which we believe will influence decision making and ultimately improve the outcomes and quality of life of the patients. Comparison with other national spine registers is possible, since FinSpine includes similar baseline characteristics and outcome measures (e.g., ODI, EQ-5D, VAS).

Keywords Spine register · Spine surgery · PROM · Outcome · Effectiveness of treatment

Introduction

Spine surgery has become a major subspecialty within orthopedic surgery and neurosurgery, covering a variety of different indications including degenerative disorders, traumas, tumors, deformities and infections. Over the last decades there has been an increase in the number of spine surgery performed [1–4]. During this time the availability of imaging has increased considerably, and there has been an excessive development of new instruments and devices. Especially for degenerative disorders the improvements in imaging have also facilitated the development of minimally invasive techniques [5].

Degenerative disorders are by far the most common indications for surgery (comprising up to 90% of all procedures in large population-based hospitals). While outcome is generally good [6–9] and evidence of improved quality of life

✉ Johan Marjamaa
johan.marjamaa@hus.fi

¹ Department of Neurosurgery, Helsinki University Hospital, Helsinki, Finland

² Department of Neurosurgery, Kuopio University Hospital, Kuopio, Finland

³ Department of Orthopedic Surgery, Helsinki University Hospital, Helsinki, Finland

⁴ Finnish Institute for Health and Welfare, Helsinki, Finland

⁵ Department of Orthopedics and Traumatology, Turku University Hospital and University of Turku, Turku, Finland

⁶ Department of Orthopedic Surgery, Central Finland Central Hospital, Jyväskylä, Finland

(QoL) is gradually increasing [10], the surgery of degenerative disorders might also be the most likely to express variations in indications and outcome. Within or between countries, variations may occur in the rate of surgeries, patient selection (including eligibility of older patients and patients with less severe symptoms), operating techniques (including use of implants) and timing of surgery [11, 12]. Variations in outcome are likely when it comes to utilization of more complex and novel techniques, where the results from the specialized centers involved in the developing process, do not necessarily translate into generalizable results.

In order to obtain comprehensive and reliable data about the surgical activity and the long-term outcomes, a comprehensive, systematic, register-based follow-up is necessary. This has earlier been performed on a high level, e.g., in Norway by the NORSpine[13] and Sweden by the SweSpine [14] registers that have provided important results which have influenced clinical practice [15]. With transparent register-based benchmarking, it could be possible to create more uniform standards among the surgeons and hopefully improve the outcomes and QoL of the patients. The real-world evidence from registers complements the evidence obtained from randomized controlled trials.

There is an increasing recognition of the importance of combining clinical outcomes with Patient Reported Outcome Measures (PROMs) and Patient Reported Experience Measures (PREMs) in order to achieve a more complete understanding of the impact and effectiveness of the treatment [16, 17]. Patients evaluate their own health, quality of life and functional status associated with the treatment they have received [18]. Thoroughly evaluated and effective interventions are more likely to have an advantageous position when prioritizing resources.

In this paper, we focus on describing the development and design of the FinSpine register. We also address the current state of nationwide implementation, compliance among surgeons to use the register and share our experience how to achieve higher response-rates from patients. Furthermore, we describe a validation process comparing the procedure codes in the FinSpine register with the same data pooled from the hospitals' Electronic Patient Records (EPRs) and show some preliminary results in order to illustrate the potential of the register.

Development and implementation of the register

Finland is a Nordic country with a population of 5.5 million. We have a wide tax funded, public health care system accessible for all citizens. Around 8500 spine surgical procedures are performed annually.

Influenced by the other Nordic countries, the idea of developing a Finnish Spine Register (FinSpine) was introduced already when the Finnish Society of Spine Surgery was founded in 2001. The development of FinSpine begun in 2014 and soon it was decided that a steering group should be formed, consisting of both orthopedic surgeons and neurosurgeons from all Hospital districts of the country. The development of the register has been done at the regular meetings of the steering group 4 times a year.

From the very beginning there was clear that the register was going to be computer-based. This would enable:

- (1) Automatic data integration from Electronic Patient Records (EPRs).
- (2) Higher compliance from surgeons to reliably fill the register with the necessary specifications of the surgeries and possible complications.
- (3) Surgeons to easily discover the patients for whom data is missing.
- (4) Real-time output of register data.
- (5) Patients to report outcome and experience measures online.

A suitable collaborator from the field of medical information technology was recruited. This company (BCBMedical) had the best technical knowledge about developing registers for healthcare in Finland. The collaboration has been good, the software has been updated at least 2 times per year according to the propositions of the steering group.

After completing the design of FinSpine our foremost goal is to validate the data and to gain a nationwide coverage of hospitals using FinSpine (currently 19/23 public hospitals). We also strive to have a high compliance among surgeons and to attain high response-rates from the patients to the PROM and PREM questionnaires. We believe that promoting the use of FinSpine this is best done by educating users at annual meetings of the Finnish Society of Spine Surgery and at dedicated FinSpine user symposiums. We have also incorporated a Report tool function into the register software which enables every surgeon to easily access the register data of their own hospital. We believe that this capability to observe one's own results and gain real-time feedback will also motivate the surgeons to use FinSpine.

Collaboration with the Finnish institute for health and welfare

In 2018 the Finnish Institute for Health and Welfare (THL), an independent expert agency working under the Ministry of Social Affairs and Health, striving to monitor, and develop measures to promote the well-being and health of the population in Finland, started a pilot for national healthcare

registers. It was proposed that the 9 most significant registers would gain a national status.

FinSpine received this lawful national status and will receive government funding from 1st of January 2023 onwards. Furthermore, THL will pool and store the FinSpine data from all the participating hospitals and provide its expertise in data handling, making it possible to easily access the entire national data. Researchers can acquire access the national data by making an application to Fin-Data, (the Social and Health Data Permit Authority operating under the guidance of the Ministry of Social Affairs and Health). The legislation is straightforward, and it is easy to compare data from different hospitals. Moreover, the national data is also accessible for researchers from outside the spine surgery community as well. We have however established a board of advisors from within the spine surgeon community to guide with the interpretation of the data and to facilitate researchers with similar interests to collaborate. Due to the collaboration with THL it is also easier to combine the register data with other national registers such as ones collecting data on drug purchase and sick leaves.

Design of the register

In Fig. 1, we show an overview of the register. Technically the register is accessible for all authorized users via a link from the Electric Patient Record software, which varies between different hospitals. The FinSpine software opens in a web browser.

Data input

A file for the patient is created real-time into the register automatically when the register software derives information that a patient is undergoing a procedure with a spine specific procedure code. In order for the data to be incorporated in the outcome reports, the register receives further input from the operating room data system. Hereby, the analysis does not include patients, or information from patients who were not eventually operated.

Each patient receives the following input of data:

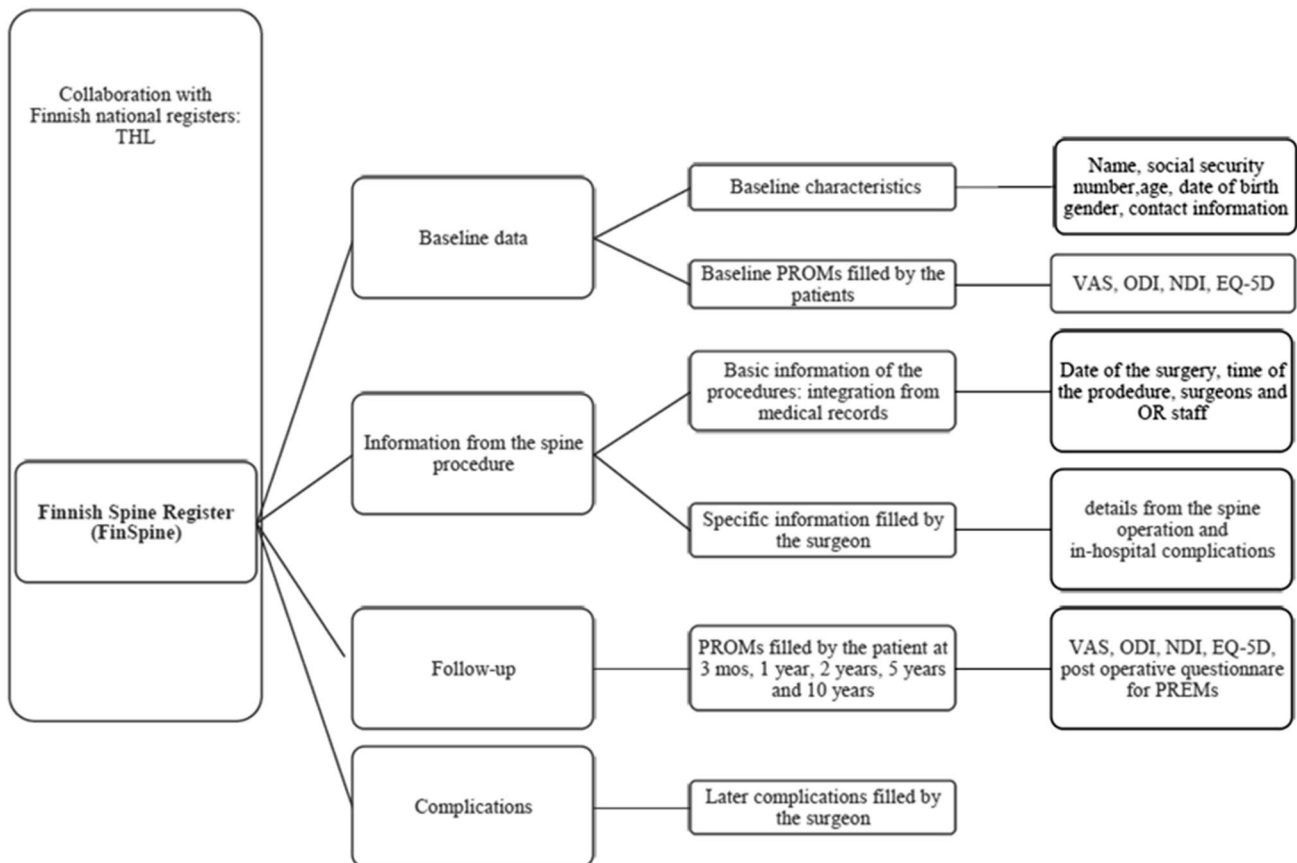


Fig. 1 Overview of the FinSpine register showing how data input is derived **A** automatically from medical records, **B** from surgeons filling specific information and **C** patients reporting PROMs and PREMs. THL is the Finnish Institute for Health and Welfare

- (1) Basic information of the surgical procedures (e.g., date, time, surgeon) automatically from EPRs
- (2) Specific information of the surgical procedures, filled by the surgeon (Table 1)
- (3) Implants that have been used (filled automatically or by OR nurse)
- (4) In-hospital complications and length of hospitalization (filled by the surgeon, see Table 1)
- (5) Later complications (filled by the surgeon if encountered, see Table 1)
- (6) Responses to PROM and PREM questionnaires filled by patients (Table 2)

The 3 steps of data the surgeon needs to fill is presented in Table 1, we have been careful only to include data we believe is relevant. On the other hand, for the listing of procedures and diseases, we have been much more detailed than what the ICD codes and procedure codes would provide. This listing corresponds with the nomenclature and definitions frequently used in scientific spine surgery publications other spine registers.

The PROMs and PREMs are presented in detail in Table 2. To obtain PROMs and PREMs, patients automatically receive a link to these questionnaires via SMS or e-mail. The link to the preoperative questionnaires is sent as soon as the operation is planned (max 60 days preoperatively) and it expires on the day of the operation. The postoperative links are sent 30 days prior to each postoperative time point (3 months, 1 year, 2 years, 5 years and 10 years) and expire 30 days past each time point. A reminder is sent 30 days after the initial link to the patients that have not responded. If a patient is re-operated within 30 days from the initial operation the time points of the following questionnaires will be according to the time points of the initial operation. However, if a re-operation is performed after 30 days, the patient will receive postoperative questionnaires with time points in reference to the last operation and will not receive duplicates from the initial operation.

Data output

The content of the register can be displayed and analyzed in different ways (Table 3).

- (1) The “Patient sheet” of individual patients, displays all details of the patient’s spine surgeries and all the responses to the PROM and PREM questionnaires. Data input by surgeons is also performed in the “Patient sheet” viewing.
- (2) The “Patient list” view enables users to easily view and sort all the patients from their own hospital by a simple

- set of variables (e.g., Patient name, Main diagnosis, Main procedure, Operating surgeon).
- (3) By using the “Report tool” function, the user can create real-time charts or plots of 20 different outcome variables (e.g., different surgeries performed, intraoperative complications, VAS, ODI, NDI), which can be filtered with 22 filters (e.g., Smoking (Y/N), Sex (F/M), Age (Range), Surgeon (Name)). This is an easy way to get insight to one’s own work and compare results with other surgeons in the same hospital (Fig. 2). Statistical testing is possible by extracting the data and using a regular statistical analysis program. For nation-wide research, the complete national register data can be accessed by making an application to FinData.

Ethical issues and data security

Data handling in hospitals and at a national level is done according to national and EU guidelines. The data is securely protected, the professionals access the register upon signing into the EPRs by using an ID and a password. Data filled by patients is GDPR compliant.

Since the PROM and PREM questionnaires are regarded general follow-up of clinical practice, no additional informed consent is needed from the patient. The patients have the right to refuse to receive the questionnaires. In order to access the national data the researcher needs to make an application to FinData, which provides expertise in data handling and data security and assures that the secondary use of data is in concordance to EU legislation and GDPR.

Validation

Validation of FinSpine against “hospital discharge register” (HILMO)

THL maintains a “hospital discharge register” (HILMO) to which all contacts, treatment periods and procedures in the whole country are registered from the hospitals’ EPRs. The HILMO register is considered highly reliable when it comes to describing these basic demographics of the Finnish health care.

In 2019 we compared all spine procedure codes from 2017–2018 in FinSpine with the ones in the HILMO register. Our hypothesis was that the FinSpine data could prove to be more accurate (since the input is generated only when both the procedure code and the trigger from the operating room data system coexist). The validation was then repeated in opposite direction.

Our hypothesis proved to be correct. The FinSpine register data proved to be 100% accurate, in terms that no patients were

Table 1 Specific and standardized information filled by the surgeon in 3 steps (in Finnish), each step taking less than 1 min. The FinSpine register includes a description of all the terms that are used, to avoid misinterpretations by the surgeons

Step 1: Specific information from the procedure (usually filled in OR)	
Target region (Cervical, thoracic, lumbar)	Procedure
Operation type	Mini-invasiveness
Primary operation (in this region of the spine C, Th, L)	Fused levels
Re-operation on different segment or side in same region	Decompressed levels
Re-operation on same segment and side as earlier	Use of grafting material
C or Th-spine myelopathy or palsy caused by nerve root -compression present?	Use of vertebroplasty or screw augmentation
L-spine Cauda equina or palsy caused by nerve root -compression presents?	Use of antibiotics
Diagnosis	Use of thrombosis prophylaxis
Herniated disk	Intraoperative complication
Recurrent hernia	NO
Central stenosis (< 3 mm olistesis)	Dural tear
Central stenosis (≥ 3 mm olistesis)	Vessel injury
Recess stenosis (< 3 mm olistesis)	Nerve injury
Recess stenosis (≥ 3 mm olistesis)	Fracture
Spondylolysis and olistesis	Spinal cord Injury
Foraminal stenosis	Other
Fracture	
Degenerated disk	
Other	
Postoperative instability	
Scoliosis	
Pseudoarthrosis	
Primary neoplasia	
Primary infection	
Metastasis	
Postoperative infection	
Postoperative hematoma	
Kyphosis	
Dislocated vertebrae	
Myelopathy	

Table 1 (continued)**Step 2: In-hospital complications and length of hospitalization:**

No complication	New radiculopathy
Delirium	Caude equine
DVT	Ileus
Urinary tract infection	Stroke
Urinary retention	Heart attack
Dysphagia and hoarseness	Implant malposition
Cervical hematoma	Wrong level surgery
Spinal hematoma	Death
Wound infection	SCI
	Other
	Length of hospitalization in days

Step 3: Later complications:

Previous ones and:
CSF fistula
Fracture
Implant failure
Implant detachment
Adjacent level disease
Nonunion

Table 2 The content of the PROM and PREM questionnaires in the FinSpine register

PROMs	PREMs
Visual analog scale (VAS)	Preoperative questionnaire
Upper limb	a. Employment (Employed, Unemployed, Retired, On Sick-leave)
Lower limb	b. Duration of pain (<6 weeks, 6–12 weeks, 12 weeks - 1 year, > 1 year)
Neck	c. Use of pain medication (No, Occasionally, Regularly)
Back	d. Smoking or use of nicotine (Yes, No)
	e. Height, weight, BMI
Oswestry disability index (ODI) for thoracic and lumbar spine	Postoperative questionnaire
	a. Knowing the results, would you choose to be operated again (Yes, No, I don't know)
	b. Are your symptoms (Better, Worse, Same)
	c. Are you satisfied with the operation (Yes, No, I don't know)
Neck disability index (NDI) for cervical spine	d. Have you gotten new comorbidities postoperatively (Asthrosis, Neurological- or Vascular disorder)
	e. Have you undergone further spine surgery elsewhere (Yes, No)
EQ-5D-5L quality of life questionnaire	f. Employment (Employed, Unemployed, Retired, On Sick-leave)
	g. Use of pain medication (No, Occasionally, Regularly)
	h. Smoking or use of nicotine (Yes, No)
	i. Height, weight, BMI

found to be missing compared to HILMO. HILMO on the other hand included unnecessary duplets of patient procedures, which distorts the overall statistics. This can be explained by the fact that the input to the HILMO register can be done twice if for example the patient awaiting surgery moves from one hospital to another. This validation will be repeated.

Intra- and interobserver validation

Intra- and interobserver validation has started and will be the subject of our future paper. We want to assess how consistent the selection of, e.g., diagnosis and procedures is among surgeons using the register.

Utility and results

The development of the register has been successful and has resulted in a computer based, user-friendly system, that has been implemented into use in the foremost departments performing spine surgery in Finland.

The first hospitals started using the register in 2016, the number of participating hospitals significantly increased in 2017 with the initiation of the collection of PROMs and PREMs. Currently 19/23 (83%) public hospitals performing spine surgery, use FinSpine and the coverage is further expanding into private hospitals, with the first ones starting to use FinSpine in the end of 2022. 7553 surgeries were included into FinSpine during 2022, which accounts for 86% of all spine surgeries performed in the whole country last year and over 90% of the surgeries performed in public hospitals.

Compliance of surgeons to use FinSpine has been steadily increasing, in 2022 80% of the cases in the register included data input from the surgeon.

The response-rates of the patients have been increasing during the last years (Fig. 3), reaching 54–58% at all the time points. However, for the patient reported data to be useful, it is necessary to obtain as high response-rates as possible. We have enhanced this by including the option of collecting responses on paper-based questionnaires and in-hospital iPads. Furthermore, we have found that up to 90% preoperative and 80% postoperative response-rates have been achieved in hospitals that have been able to hire register coordinators, who contact the patients by phone and remind the about the questionnaires and can systematically send them paper-based questionnaires if the responses are lacking.

Examples of outcomes

In Table 4, we show the cumulative data from 2017 to the present, showing the 5 most common diagnosis for Lumbar

Table 3 Different ways to display data of FinSpine

1) Contents of register viewing	2) Report tool outcome variables and filters	3) National data accessible via FinData
Content of Patient list:	Variables:	Filters:
ID	Diagnosis (main and additional) number of cases	Age
Name	Diagnosis % of cases	Agegroup
Main Diagnosis	Surgeries, number of cases	Antibiotics
Main Procedure	Surgeries % of cases	Assistant
Date Procedure	Fusion levels	Body Mass Index
Target for operation (C, Th, L)	Fusion length	Comorbidities
Operating surgeon	Decompression levels	Department
Assistant	Decompression length	Graftbone used
Specific information from procedures (filled by the surgeon) missing yes/no PROMs answered yes/no	Intraoperative complications amount	In-hospital complication
Dead / alive	Intraoperative complications %	Intraoperative complication
	In-hospital complications amount	Main diagnosis
Content of Patient sheet:	In-hospital complications %	Main procedure
ID, Name, contact information	Length of hospitalization (days)	Preop of ca jda equina
All spine related diagnosis	Backpain (VAS)	Preop of myelopathy
All spine related procedures	Neckpain (VAS)	Preop of radicular pain
Dates of procedures and outpatient visits	Lower limb pain (VAS)	Preop of paresis from rootcompression
Specific information from the procedures (see Table 2)	Upper limb pain (VAS)	Primary- or re-operation
All identified complications	ODI	Sex (M/F)
All PROM and PREM data from the specific patient	NDI	Smoking
	Satisfaction to surgery	Surgeon
	Later comorbidities	Target for operation (C, Th,Lj
		Thrombosis profylaxis

Register data from each hospital can be viewed and sorted in a “Patient list” view. The “Patient sheets” of individual patients can be opened to access all data of each patient

The “Report tool” function can be used to create real-time charts or plots of 20 different outcome variables. These reports can be filtered with 22 filters. The reports are descriptive (boxplots, bar charts or histograms displaying n, range, SD, mean, median if applicable) and do not show the identity of the patient

Complete national data can be accessed by an application to FinData

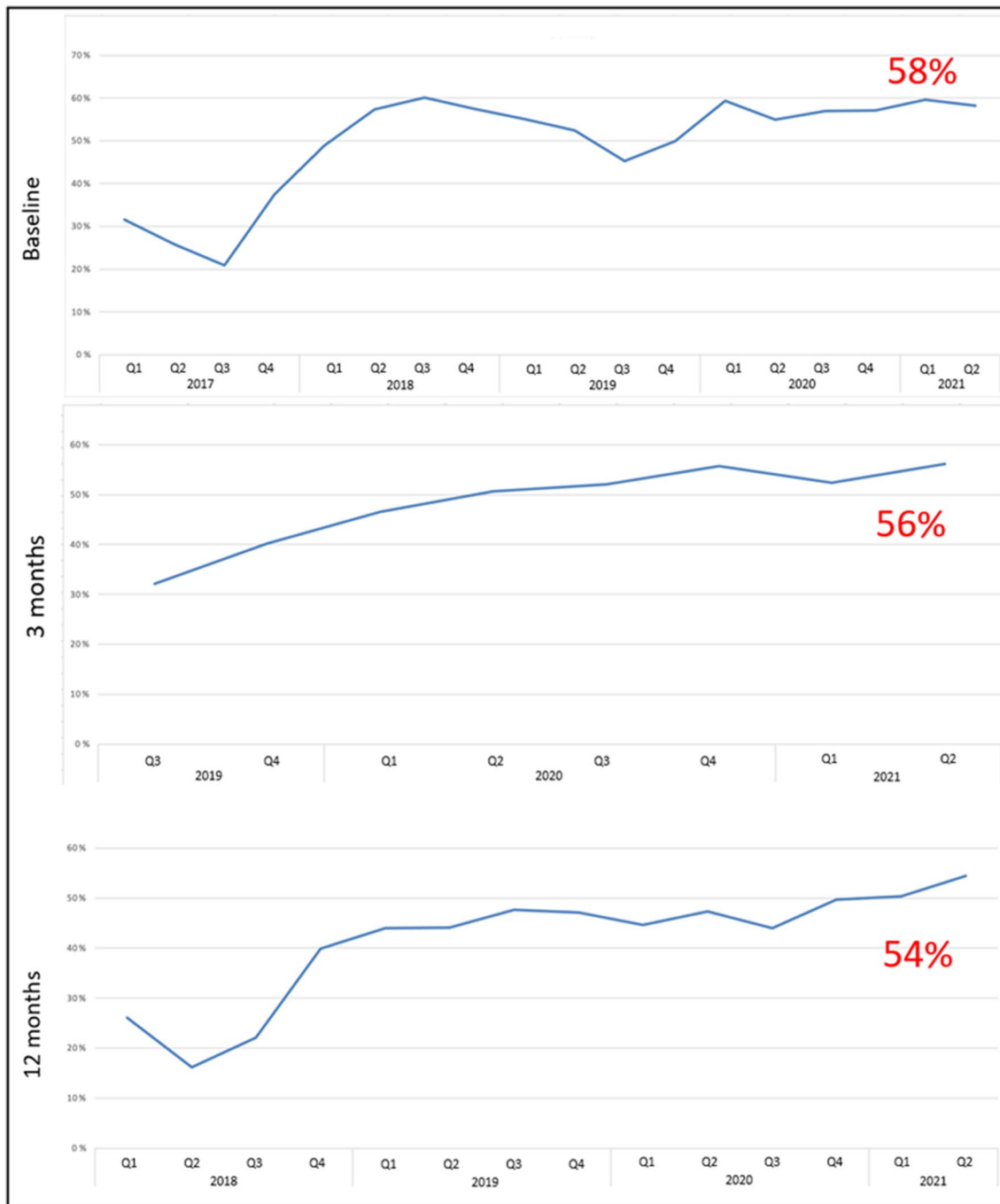


Fig. 3 The development of the response rate for the PROM and PREM questionnaires in the FinSpine register. The baseline data has increased from <30% in 2017 to 58% in 2021. The same is observed also for 3 mos and 12 mos timepoints

full- or part-time coordinators who directly contact the patients, remind them and send paper-based questionnaires if needed. Patients can also give their response while visiting the hospital by using a portable device (iPad) that connects to the register software.

5. Including data from conservatively treated spine patients.

This data would be imprecise and incomplete since most conservatively treated patients are treated elsewhere. Only patients undergoing surgery are included.

Table 4 Statistics derived from FinSpine showing the 5 most common indications for Lumbar and Cervical surgeries reported to the FinSpine register 2017–2022

Lumbar spine		Cervical spine	
Diagnosis	n	Diagnosis	n
Herniated disk	4647	Foraminal stenosis	1829
Central stenosis (< 3 mm olis- tosis)	4355	Herniated disk	1210
Central stenosis (> 3 mm olis- tosis)	2030	Central stenosis (< 3 mm olis- tosis)	856
Recess stenosis (< 3 mm olis- tosis)	1637	Fracture	499
Spondylolysis and olistesis	897	Myelopathy	252
Overall	16,700	Overall	5412

6. Expenses of development.

All participating departments initially needed to acquire funding from the hospitals. We were able to perform this quite easily by backing up each other and by making the importance of the content clear to the hospital board. The large number of participating departments also lowered the expenses.

Technically FinSpine was developed to be computer-based in order for it to be easy to use and in order to automatically send questionnaires to the patents. During the years of use it has become apparent that though patient response-rates have steadily increased the average response-rate of 54–58% is not sufficient for detailed analysis of the results. Therefore, we found it necessary to hire coordinators

who contact the patients and if necessary, send patients paper-based questionnaires as well. In hospitals with full-time coordinators response rates of up to 90% preoperatively and 80% postoperatively have been achieved. However, our data does not show a difference in response rates between younger and older patients, but we will do further analysis on which different patient related factors can affect the response rate. With government funding we hope to introduce coordinators to the hospitals still lacking one.

Better compliance among surgeons has been achieved by motivating and educating the surgeons regularly at annual meetings of the Finnish Society of Spine Surgery and at dedicated FinSpine symposiums. We also believe that presenting results is a way to motivate the users, e.g., by displaying inter-hospital variations in the completeness of the register to surgeons and coordinators. Surgeons can also acquire real-time feedback by using the Report tool of FinSpine. Surgeons are also compelled to fill information regarding possible in-hospital and later complications meticulously. We do not know yet whether there is inconsistency between surgeons in reporting possible complications.

Validation of the variables within the register has been started. So far, we found that the FinSpine register data included all the cases reported to the national hospital discharge register, with no patients missing. We are currently performing an intra- and interobserver validation to assess how consistent the use of FinSpine is. Accumulating national data, collected identically in each hospital allows valid benchmarking between hospitals. On the THL website, the first report regarding outcome after lumbar discectomy will be displayed, depicting intraoperative complications and

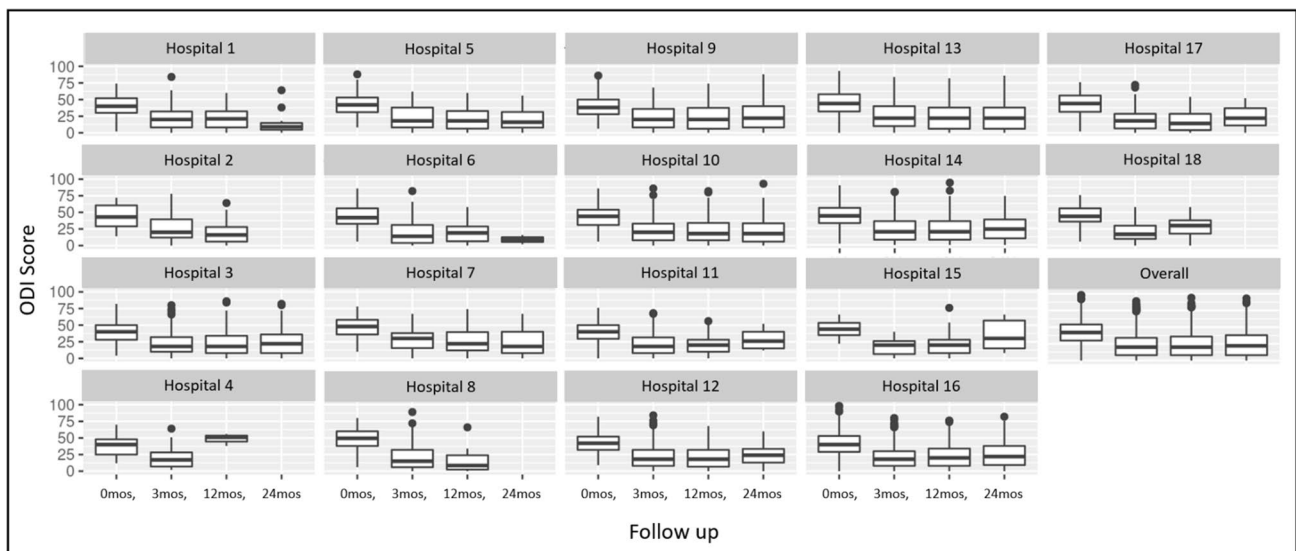


Fig. 4 The pre- and postoperative (3 mos, 12 mos, 24 mos) ODI Scores in the FinSpine register for all patients undergoing surgery for lumbar spinal stenosis is shown for each hospital. In the lower right

corner is the combined overall result. An overall of 9129 patients were operated, case-mix has not been taken into account

the postoperative VAS reported by the patients for from the different hospitals.

In modern medicine there is an increasing interest in studying the effectiveness of care of different disorders. The assessment of real-life effectiveness and real-life cost-effectiveness requires the existence of patient group specific quality registers which document data on patients, interventions and outcomes in ordinary health and social care [19–21]. We believe that data from national spine registers will influence decision-making and improve the outcomes and QoL of the patients.

Thoroughly evaluated and effective interventions are likely to confirm their position in future. Displaying reliable and transparent reports of register data is set to add confidence toward spine surgery. Spine surgeons in different countries are urged to develop similar registers.

Conclusions

FinSpine has established its position in the Finnish spine surgery community, while further work to achieve higher response-rates and even wider coverage is being done. We believe that FinSpine could be as influential as the other national spine registers. Utilization of FinSpine data in order to assess quality and perform scientific research is already being done. First reports of outcomes will be displayed on the THL website. FinSpine can serve as a reference for national or international studies. In future, we hope to collaborate with other national registers and conduct inter-register analysis.

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